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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,498	12/04/2000	Joseph J. Kircher	NU-5532	3314

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/729,498	KIRCHER ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *10 July 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

1. The drawings were received on July 10, 2003. These drawings are acceptable.

Response to Arguments

2. Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive. Applicant's arguments are directed to the capability of the computing means to store data, determine the compatibility of pharmaceutical components, and determine the order in which the components are mixed. Applicant argues that Lewis et al. US 5,228,485, teaches a device in which an operator is required to program the device in order for it to perform the above functions.

The examiner asserts that all computers or automated devices must be programmed at some point in order for it to function. Therefore, applicant's device must be equipped with a table or data which has been entered or collected by an operator. It is understood that technology does exist which allows a computer to "learn" after its been initially programmed to function or run specific routines.

It appears that the issue of the patentability of the instant invention and that of Lewis may be the ability of the computer or control means to "learn" or time at which the operator inputs data (neither of which is encompassed by the breathe of the claim).

In column 6, lines 44-53 of Lewis et al. teaches:

"The **control means** may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber **if the first and second fluids are compatible** with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. **The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber.** The control means 32 enhances fluid flow from the chamber 18 into the receiving container 24 by causing the pressure means to generate a positive pressure in pressure conduit 26 which is in fluid communication with the chamber 18. This causes a positive pressure in the chamber so that when the second occlusion means 30 is opened to allow fluid to flow from the chamber to the receiving container 24, the positive pressure will force the fluid out of the chamber and into the receiving container 24. This greatly reduces fluid retention in the chamber 18."

As recited above, the control means does have the ability of determining if the components are compatible and altering the order of dispensing when properly programmed.

The issue of the device being programmed by an operator has no patentable weight on the claimed material for as recited herein above and below the control means does determine the compatibility of the components and whether or not a fluid is dispensed (order of dispensing).

For the reasons given herein, the examiner hereby maintains the previous rejection of paper no. 8.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 10, 24-27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. US 5,228,485.

Lewis et al. discloses an invention that generally relates to systems for transferring fluids from individual source containers to a receiving container, and more specifically relates to systems for transferring liquid drugs from individual vials, bottles, or bags to a single solution bag or bottle for administration to a patient.

In hospitals, it is frequently necessary to provide solutions for intravenous administration to a patient which contain a variety of drugs in a single solution container. A common example of such a need arises when a patient is receiving all of his nutritional needs intravenously. In this situation, the patient will typically receive a basic

solution containing amino acids, dextrose, and fat emulsions which provide a major portion of the patient's nutritional needs (prescriptions). However, this solution is insufficient to maintain a patient for an extended period of time. Therefore, a typical total parenteral solution includes as many as eight to twelve additional additives. The additives are typically minute quantities of vitamins, minerals, electrolytes, etc. Therefore, when a pharmacist is preparing a solution for total parenteral nutrition, it is necessary for the pharmacist to individually add each of the additional additives to a solution container after the base solutions have been added. This is typically done with individual syringes and requires a relatively long time on the part of a pharmacist to accurately add all additives to each of the required additives.

An object of the invention is to provide a means for periodically flushing the measuring chamber described above to rinse the chamber of any incompatible drugs. In accordance with the invention, a device 10 (FIG. 1) is provided for accurately transferring individual doses of separate fluids from individual source containers 12. Each individual source container may contain a different fluid 14. In some cases, the fluid in one container may be incompatible with fluids contained in other source containers. According to the invention, fluid is transferred from each source container 12 through a separate individual fluid conduit 16 to a single chamber 18. The chamber 18 is suspended from a load cell assembly 20. The load cell 20 constantly weighs the total weight of the chamber to develop an output signal which is indicative of the amount of fluid in the chamber 18 at any given time.

The device comprises a control means that may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber if the first and second fluids are compatible with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber (which inherently implies that the device may be programmed to compare pharmaceutical components relative to one another allowing the order of dispensing to be determined).

After a transfer set has been installed in the device, the operator is then ready to program the device to indicate the amount and type of each fluid to be transferred from each of the individual source containers into the receiving container. Information can be input into the device from one of two sources. One source of entering information into the device is a keyboard entry device, illustrated in FIG. 22.

When the device is turned on, a system of internal checks is automatically performed by the control means 32. In the preferred embodiment of the invention, two microprocessors are used in the control means 32. While a variety of microprocessors can be used, in one embodiment of the invention, an Intel 8031 microprocessor can be used for both of the microprocessors. One microprocessor serves as a master microprocessor and another microprocessor serves as a pumping control microprocessor. A simplified block diagram of a typical microprocessor is illustrated in FIG. 23. As can be seen in this figure, a typical microprocessor includes an internal

random access memory 222 and a plurality of in/out (I/0) ports 224. The microprocessors include a variety of hardware registers which can be programmed to perform special functions. In the preferred embodiments of the subject invention, the special function hardware registers 226 may include serial interface registers 228, timer/counters 230, and a stack pointer 232. Each of these aspects of the microprocessor as used in the preferred embodiment of the subject invention will be discussed in greater detail below. In addition to the internal features of a typical microprocessor as briefly described above, additional external hardware is present in a typical microprocessor control device. For example, an external RAM 234, external in/out ports 236(LAN connection), and a programmable memory (ROM) 238 are required to allow a microprocessor to perform the desired functions in accordance with the invention.

FIG. 26 illustrates a display panel for displaying volumetric and specific gravity information for each source container. The display panel displays the specific gravity as programmed by an operator for a particular source container as illustrated by LCD display panel 250. The volume of fluid to be transferred from a specific source container to the receiving container as programmed by an operator is illustrated by another LCD display panel 252. Each individual source container has separate LCD display panels 250 and 252 for displaying the specific gravity and volumetric information for each source container.

The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, during initial set up of the device, the specific gravity for each source container will be initially programmed by the operator.

If the pump control microprocessor is ready to receive data, the master microprocessor computes (conversion) the weight of fluid to be transferred from each individual source container to the receiving container given the volume and specific gravity information input in the device during the keyboard entry mode. This computation is essentially identical to the computations described in U.S. Pat. No. 4,513,796 entitled "High Speed Bulk Compounder" issued Apr. 30, 1985. This application is incorporated herein by reference. The pump control routine checks to see if any of the information entered by the operator is out of a predetermined range. For instance, in the preferred embodiment of the invention, the allowable range for specific gravity is between approximately 0.5 and 3.0. The minimum volume to be transferred has to be, for example, at least one milliliter in the preferred embodiment of the invention. If any of the information is determined to be outside of these ranges, the pump control routine notifies (alarms) the operator by causing the display 250 or 252 (FIG. 26) which is out of range to flash. This is illustrated by block 302 in FIG. 28.

The drain routine is simply a series of checks to determine if the chamber needs to be drained. The first check performed by the drain routine is to determine if the last source container has been pumped. This check is illustrated by decision diamond 506 in FIG. 36. If the last source container has not been pumped, the drain routine next checks to see if a rinse is to follow the source container that was just pumped. This check is

illustrated by decision diamond 508. Normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped. The next check performed by the drain chamber routine is to determine if the next source container to be pumped is supposed to be followed by a rinse. This is illustrated by decision diamond 510. In the preferred embodiment of the invention, if the next source container is to be followed by a rinse, then a drain operation will occur prior to filling the chamber with that fluid.

Claim Rejections - 35 USC § 103

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5-23 and 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, 24-27, and 29 above, and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*; Baxter May 1999.

Lewis et al. does not specifically recite that the pharmaceutical components comprises groups consisting of lipids and sterile water.

Baxter discloses a method of operating or programming an apparatus for compounding in which the patient and prescription data, performance of compounding calculations, printing reports, and support of the nutritional solution is detailed.

Three levels of user passwords including Administrator, Pharmacist, and Technician manage access to the programs of the device. The device also requires that patient's profile be entered when creating a prescription. The profile includes such information as the patient's weight, age, name, as well as the patient type (adult, pediatric, neonate, etc.) (see 2-5). As seen on the display of page 2-16 one of the components may be sterile water and Lipids as given on page 2-19. Before the prescription of a patient is compounded and verified via password, a series of validity tests are performed to warn the user producing warnings for overfill, electrolyte, osmolarity, ingredient volume, patient weight, and calcium phosphate solubility (pages 2-24 – 2-26). As seen on pages 3-4 and 3-5 the phosphate additive is added before the calcium additive. The device is also capable of maintaining history logs of the patients information.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that lipids and sterile water may be components of the pharmaceutical components for Baxter discloses that these are common components used in the development of nutritional needs for adult, neonatal, and pediatric patients.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
September 17, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700